

**HOME HEALTH TECHNOLOGY CO., LTD.**

K043376 1/2

NO. 77. Gongye Rd. Dalli city

Taichung county 412, Taiwan, R.O.C.

JAN 10 2005

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**“ 510(k) SUMMARY ”**

Submitter's Name: ***Home Health Technology Co., Ltd.***

NO. 77. Gongye Rd. Dalli city Taichung county 412, Taiwan, R.O.C.

Date summary prepared:

November 27, 2004

Device Name:

Proprietary Name: Home Health Power Wheelchair, HC-200TR

Common or Usual Name: Powered Wheelchair

Classification Name: Powered Wheelchair, Class II,  
21 CFR 890.3860

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a seated position.

Description of the device:

The Home Health Power Wheelchair, HC-200TR is an indoor / outdoor Powered Wheelchair that is battery operated. It has a base with four-wheeled with a seat. The movement of the Wheelchair is controlled by the rider who uses hand controls located at the top of the steering column. The device can be disassembled for transport, the seat can be tilted and reclined, and is provided with an onboard battery charger.

Performance Testing:

EMC Report ANSI / RESNA WC/Vol.2-1998, CISPR 11: 1990, EN61000-3-2: 1995, IEC61000-3-3: 1995 (Electrically Powered Wheelchairs, controller, and their chargers – requirements and test methods)

Legally marketed device for substantial equivalence comparison:

SINON Power Wheelchair, SN-P401 (K040320)

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**C.2 COMPARISON SUMMARY**

*( We place the related information for the predicate device in the following pages. )*

We can know from the above table that the intended use between two devices is the same. The **batteries** used are the same brand and similar U1 type. The **control** systems for the two devices are used from same brand and different types: Dynamic SHARK for the new device, and Dynamic DL for the predicate device. The **recharge** for the two devices are also used the same supplier, and the chargers are also certified by UL. Besides, the removable **armrest type**, same **casters size**, same **incline**, and **back upholstery** are the same material that also be passed the resistance ignition test by SGS.

The cruising range of the new device is 25 miles and 20 miles for the predicate device. This is mainly due to the fact that the batteries for the two devices are smaller. Certainly the real range depends on the practice environments, i.e., weight, surface, incline, and temperature. For the real life use, the two devices are substantially equivalent.

The maximum speed for the new device is 5 mph and 4 mph for the predicate device. Higher speed means the new device shall meet relevant requirements for the braking time, distance, and dynamic stability for safety considerations. The different maximum speeds do not lead any safety considerations and they are substantially equivalent in this aspect.

To sum up the mainly different of the two devices are only appearance dimensions, i.e., the overall dimensions, the size of wheels, seat dimensions, and weight limit. Besides the seat of the new device can be tilted and reclined. For the regular operator, these differences for the two devices do not lead to any performance differences, and the two devices are substantially equivalent.

*Based on the above the information and the analysis, we know that the subject device, the predicate device have the same intended use the same technological aspects and only minor dimensions and material differences exist. We believe that FDA can decide the subject device and the predicate device are substantially equivalent.*



JAN 10 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Dr. Jen, Ke-Min  
C/o Roc Chinese-European Industrial Research Society  
No.58, Fu-Chun ST.  
HSIN-CHU CITY, Taiwan, ROC

Re: K043376

Trade/Device Name: HOME HEALTH Power Wheelchair, HC – 200TR  
Regulation Number: 21 CFR 890.3860  
Regulation Name: Powered wheelchair  
Regulatory Class: II  
Product Code: ITI  
Dated: November 27, 2004  
Received: December 8, 2004

Dear Dr. Ke-Min:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

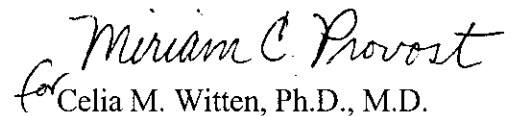
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

  
for Celia M. Witten, Ph.D., M.D.

Director  
Division of General, Restorative and  
Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510 (K) Number ( If Known ): K043376

Device Name: HOME HEALTH Power Wheelchair, HC-200TR

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

Prescription Use \_\_\_\_\_

AND/OR

Over-The-Counter Use ✓

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

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